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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 378/03474	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IL 03/00995	International filing date *(day/month/year)* 25.11.2003	Priority date *(day/month/year)* 25.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M25/01		
Applicant F.D. CARDIO LTD. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 14 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.05.2004	25.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Pascal-Moussellard, Telephone No. +49 30 25901-555

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL 03/00995

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-37 as originally filed

Claims, Numbers

1-137 filed with telefax on 14.09.2004

Drawings, Sheets

1/24-24/24 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 115-137

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 115-137 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-114
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-114
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-114
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Although claims 1, 115, and 124 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Due to above mentioned multiplicity of independent claims seeking to define more or less the same invention in different ways, it seems not feasible to perform a substantive examination on all the claims. Independent claim 1 seems best to define the idea underlying to present application. The substantive examination is therefore being based on claim 1 and subsequent dependent claims.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-B-6 248 1121 (GAMBALE RICHARD A ET AL) 19 June 2001 (2001-06-19)
D1: US-A-5 308 354 (ZACCA NADIM M ET AL) 3 May 1994 (1994-05-03)
D2: US-B-6 254 6111 (VRBA ANTHONY C) 3 July 2001 (2001-07-03)

Claim 1 is not clear. The examination of claim 1 and subsequent dependent claims has been done on the basis of claim 1 amended as following : "a catheter for use in a blood

vessel, comprising:
an elongate body having an axis, a lumen along said axis, a proximal opening at one end, connected to the lumen and a front tip at a distal end of the body;"
a second elongate body, "wherein said elongate body is configured for axial motion of at least 50 mm relative to said second elongate body" (note: word "section" removed); and "an elongate hydraulic fluid column in said lumen and adapted to apply a pushing force to said front tip in a distal direction, said force being applied at an application point, said force being suitable for extending said tip at least 50 mm relative to said elongate body."

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):
a catheter for use in a blood vessel, comprising:
an elongate body having an axis, a lumen along said axis, a proximal opening at one end (" the delivery catheter comprises an elongate shaft that contains pressurized fluid within its lumen to motivate a plunger located at the distal end of the shaft . The fluid pressure delivery device 90 comprises an elongate shaft 92 having at least one lumen 94, which carries the pressurized fluid 96" see D1 col.9 l.38-41 and fig.8), connected to the lumen and a front tip at a distal end of the body; a second elongate body, wherein said elongate body is configured for axial motion; and an elongate hydraulic fluid column in said lumen and adapted to apply a pushing force to said front tip in a distal direction, said force being applied at an application point ("The distal portion 102 of the lumen 94 is configured as a track 104 to receive a slidable plunger 106 that forms a fluid tight seal with the track. Fluid pressure within the lumen 94 creates a force against the plunger causing it to slide distally." see D1 col.9 l.50-53 and fig.8).
The subject-matter of claim 1 differs from this known catheter in that the relative axial motion between the elongate bodies is at least 50 mm.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to extend a catheter tip at least 50 mm applying a pushing force through a pressurized hydraulic fluid column.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

none of the documents cited in the search report suggests or hints to a said solution in order to solve said problem. The axial motion of the tip in D1 is limited and the device described therein can not be used for such a distance.

Claims 2-114 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Remarks: Upon entering regional phase, the following should be noted:

Independent claim 1 should be redrafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Claim 34 which is superfluous and redundant with the characterising part of claim 1 should be deleted.

Mention the relevant background art disclosed in the documents D1 and D2 in the description, and identify these documents therein (Rule 5.1(a)(ii) PCT).

CLAIMS

1. A catheter for use in a blood vessel, comprising:

an elongate body having an axis, a lumen along said axis, a proximal opening at one end, connected to the lumen and a front tip at a distal end of the body; and

an elongate hydraulic fluid column in said lumen and adapted to apply a pushing force to said front tip in a distal direction, said force being applied at an application point.

2. A catheter according to claim 1, wherein said application point is nearer said front tip than said proximal opening.

3. A catheter according to claim 1 or claim 2, wherein said proximal opening is adapted to be outside a human body, when the catheter is in use.

4. A catheter according to any of claims 1-3, wherein said catheter is configured so that said liquid material does not drain into said blood vessel.

5. A catheter according to any of claims 1-4, wherein said column is adapted to be advanced from outside a body.

6. A catheter according to any of claims 1-5, wherein said body comprises a collapsed tube which extends from said tip to outside of said body and which said pushing force extends collapsed tube.

7. A catheter according to any of claims 1-6, wherein said tip pulls along a portion of said catheter, having a length of at least 5 times a diameter of the catheter, said length being pulled by said tip when pushing force is applied to said tip.

8. A catheter according to any of claims 1-5, wherein said body comprises a first, inner, tube and a second, outer tube, said tubes at least partially axially overlapping, wherein said pushing force extends one tube relative to the other tube.

9. A catheter according to claim 8, wherein said tip pulls at least a portion of said one tube with it when pushing force is applied to said tip.

10. A catheter according to claim 9, wherein said pulled section is too soft to be reliably pushed a distance of more than 500 mm in a human body, when the catheter is in use.

11. A catheter according to any of claims 9-10, wherein said tip pulls along a tube other than said tubes when pushing force is applied to said tip.

12. A catheter according to any of claims 9-11, wherein at least a portion of said one tube is adapted to be stored outside a human body when the catheter is in use and extends out of a catheter base of said catheter.

13. A catheter according to any of claims 9-11, wherein at least a portion of said one tube is adapted to be stored outside a human body, when the catheter is in use, in a configuration having a shortened axial dimension.

14. A catheter according to any of claims 8-13, wherein said inner tube extends when said force is applied.

15. A catheter according to any of claims 8-13, wherein said outer tube extends when said force is applied.

16. A catheter according to any of claims 8-13, wherein only one of said inner and said outer tubes substantially extends when said force is applied.

17. A catheter according to any of claims 8-16, wherein said fluid column is carried between said two tubes.

18. A catheter according to any of claims 8-16, wherein said fluid column is carried within the inner tube.

19. A catheter according to any of claims 8-18, comprising a tool attached at said tip.

20. A catheter according to claim 19, wherein said tool comprises a balloon attached at said tip.

21. A catheter according to claim 20, comprising a separate tube with a lumen for inflating said balloon.

22. A catheter according to claim 20, wherein said balloon is attached to a metallic inflation tube.

23. A catheter according to claim 20, wherein said inner tube serves as a lumen for inflating said balloon.

24. A catheter according to claim 23, wherein said inner tube serves as a lumen for inflating said balloon and not for said fluid column.

25. A catheter according to claim 20, wherein said balloon is inflated via a lumen which carries said fluid column.

26. A catheter according to claim 25, wherein said balloon is inflated using a higher pressure than used for extending said catheter.

27. A catheter according to claim 25, comprising a valve at said balloon for selectively allowing liquid flow into said balloon.

28. A catheter according to claim 27, wherein said valve is a pressure sensitive valve.

29. A catheter according to claim 27, wherein said valve is an externally actuated valve.

30. A catheter according to claim 29, wherein said valve is a stop valve in which a block is retracted from a port to said balloon to allow fluid under pressure to enter the balloon.

31. A catheter according to claim 29, wherein said valve is a rotating stop valve having at least two configurations, and in which a block is rotated from one configuration to a second one of said configurations to selectively seal or not seal a port to said balloon.

32. A catheter according to claim 21, wherein said balloon inflation tube is adapted to be stored outside a human body, when the catheter is in use.

33. A catheter according to claim 32, wherein said tube is stored in an axially collapsed state.

34. A catheter according to any of claims 8-33, wherein said tube is adapted to extend at least 50 mm.

35. A catheter according to any of claims 8-33, wherein said one tube is adapted to extend at least 150 mm.

36. A catheter according to any of claims 8-33, wherein said one tube is adapted to extend at least 250 mm.

37. A catheter according to any of claims 8-33, wherein said one tube is adapted to extend no more than 500 mm.

38. A catheter according to any of claims 8-33, comprising at least one stop which prevents relative motion between the two tubes greater than a pre-set distance.

39. A catheter according to claim 38, wherein at least one of said at least one stop is outside of said body.

40. A catheter according to claim 38, wherein at least one of said at least one stop is not in contact with said fluid.

41. A catheter according to claim 38, wherein said at least one stop comprises a wire extending out of said catheter and at least one movable brake section mounted on said wire.

42. A catheter according to claim 38, wherein said stop, when engaged, prevents liquid flow therethrough.

43. A catheter according to claim 38, wherein said stop, when engaged, does not prevent liquid flow therethrough.

44. A catheter according to claim 38, wherein said stop, is located within 50 mm of a proximal end of the extending tube.

45. A catheter according to claim 38, wherein said stop, is located at a distance of at least 50 mm from a proximal end of the extending tube.

46. A catheter according to claim 38, wherein when said tube is fully extended, said stop is located at a distal end of the non-extending tube.

47. A catheter according to claim 38, wherein when said tube is fully extended, said stop is located at a position spaced less than 50 mm from a distal end of the non-extending tube.

48. A catheter according to claim 38, comprising a plurality of axially spaced stops.

49. A catheter according to claim 38, wherein said stop is an element axially shorter than 5 mm.

50. A catheter according to claim 38, wherein said stop is an element axially longer than 5 mm.

51. A catheter according to any of claims 8-50, comprising at least one seal between said tubes.

52. A catheter according to claim 51, wherein said at least one seal is adapted for a particular outer tube inner diameter.

53. A catheter according to claim 51, wherein said at least one seal is adapted for a range of outer tube inner diameters.

54. A catheter according to claim 51, wherein said at least one seal comprises a plurality of axial spaced seals.

55. A catheter according to claim 51, wherein said at least one seal comprises only a single seal.

56. A catheter according to claim 51, wherein said at least one seal acts as a stop for preventing over-extension of said one tube.

57. A catheter according to any of claims 8-56, comprising an extension limiter which prevents steps of extension greater than a pre-set distance.

58. A catheter according to claim 57, wherein said pre-set extension step limitation is user-settable.

59. A catheter according to any of claims 8-58, comprising a lock configured to selectively lock said inner tube to said outer tube and preventing motion.

60. A catheter according to any of claims 8-59, comprising a lock configured to selectively couple said other tube to said body.

61. A catheter according to any of claims 8-60, comprising a pressure valve configured to release pressure of said working fluid above a certain liquid pressure.

62. A catheter according to any of claims 8-61, comprising a controller configured to control extension of said one tube.

63. A catheter according to claim 62, wherein said controller is adapted to extend said tube by a controlled amount.

64. A catheter according to claim 62, wherein said controller is adapted to extend said tube by setting a pressure level to be achieved in said liquid.

65. A catheter according to claim 62, wherein said controller is adapted to advance said catheter.

66. A catheter according to claim 62, wherein said controller is adapted to synchronize a locking of said catheter with inflation of a balloon portion of said catheter.

67. A catheter according to claim 62, wherein said controller is adapted to retract said tube relative to said catheter.

68. A catheter according to claim 67, wherein said controller is adapted to synchronize said retraction with advancing of said catheter.

69. A catheter according to any of claims 8-68, comprising a guiding sheath surrounding said tubes.

70. A catheter according to any of claims 8-69, comprising a guide wire, wherein said catheter is adapted to ride on said guide wire.

71. A catheter according to claim 70, wherein said catheter is configured so that said guide wire passes through said inner tube to outside a human body, when the catheter is in use.

72. A catheter according to claim 70, wherein said catheter is configured so that said guide wire passes between said inner tube and said outside tube to outside a human body, when the catheter is in use.

73. A catheter according to claim 70, wherein said catheter is configured so that said guide wire passes outside of said outside tube to outside a human body, when the catheter is in use.

74. A catheter according to claim 70, wherein said catheter is configured so that said guide wire passes outside of a guiding sheath to outside a human body, when the catheter is in use.

75. A catheter according to claim 70, comprising a balloon at said tip.

76. A catheter according to claim 75, wherein said guide wire passes through an inflation lumen of said balloon.

77. A catheter according to claim 75, wherein said guide wire has a proximal exit from said balloon adjacent said balloon.

78. A catheter according to claim 77, wherein said balloon has a thick base from which said guide wire exits.

79. A catheter according to claim 77, wherein said exit is less than 20 mm from said balloon.

80. A catheter according to claim 77, wherein said guide wire passes within an inflation lumen of said balloon.

81. A catheter according to claim 75, wherein said guide wire exits said catheter from said extending tube at a point distal from a most distal point of said non-extending tube.

82. A catheter according to claim 75, wherein said guide wire exits said catheter from said extending tube at a point proximal to a most distal point of said non-extending tube.

83. A catheter according to claim 75, wherein said guide wire passes through a seal between the two tubes.

84. A catheter according to claim 75, wherein said guide wire passes a through a liquid path of said column in said catheter.

85. A catheter according to claim 75, wherein said guide wire passes only outside of a liquid path of said column in said catheter.

86. A catheter according to any of claims 8-85, wherein said inner tube comprises a standard balloon catheter, not manufactured for fluid control and wherein said liquid is carried between said outer tube and said standard balloon catheter.

87. A catheter according to any of claims 8-85, wherein said inner tube comprises a standard balloon catheter having an adjustable seal mounted thereon, and wherein said liquid is carried between said outer tube and said standard balloon catheter.

88. A catheter according to claim 87, wherein said outer tube is a guiding catheter.

89. A catheter according to any of claims 8-88, wherein said outer tube has an outer diameter of less than 3 mm.

90. A catheter according to any of claims 8-88, wherein said outer tube has an outer diameter of less than 2 mm.

91. A catheter according to any of claims 8-88, wherein said outer tube has an outer diameter of less than 1 mm.

92. A catheter according to any of claims 8-91, wherein said inner tube has an outer diameter of less than 1.5 mm.

93. A catheter according to any of claims 8-91, wherein said inner tube has an outer diameter of less than 0.5 mm.

94. A catheter according to any of claims 1-93, wherein said application point is less than 500 mm from a most distal point of said catheter.

95. A catheter according to any of claims 1-93, wherein said application point is less than 350 mm from a most distal point of said catheter.

96. A catheter according to any of claims 1-93, wherein said application point is less than 70 mm from a most distal point of said catheter.

97. A catheter according to any of claims 1-93, comprising an offset element between said application point and said tip, which application point conveys said force from said column towards said tip.

98. A catheter according to any of claims 1-97, comprising a push wire adapted to apply a second force to said tip.

99. A catheter according to claim 98, wherein said push wire applies said second force at a substantially same axial position as said application point.

100. A catheter according to claim 98, comprising a controller configured to allow a short advance of said wire, suitable for passing a narrowing in a blood vessel.

101. A catheter according to any of claims 1-100, comprising a base hub adapted to remain outside a human body, when the catheter is in use.

102. A catheter according to claim 101, wherein said base hub has only a single port for liquid pressure.

103. A catheter according to claim 101, wherein said base hub has a plurality of ports for liquid pressure.

104. A catheter according to claim 103, wherein at least one of said ports has a cover adapted to remain closed when fluid inside said port is at 5 atmospheres of pressure or more.

105. A catheter according to claim 101, wherein said base hub comprises a pressure release valve.

106. A catheter according to claim 101, wherein said base hub comprises a port for a guide wire.

107. A catheter according to claim 101, wherein said base hub comprises a port for a pushing wire.

108. A catheter according to claim 101, wherein said base hub comprises a port for a valve control wire.

109. A catheter according to claim 101, wherein said base hub comprises a port for an extension restricting wire.

110. A catheter according to claim 109, wherein said port is configured to lock said wire when said base is pressurized above a pre-set pressure value.

111. A catheter according to claim 101, wherein said base hub comprises a selector configured for selecting which of a plurality of lumens of the catheter fluid pressure will be coupled to.

112. A catheter according to claim 101, wherein said base hub comprises a closable opening suitable for selectable user access to a lumen of the catheter through the door.

113. A catheter according to claim 112, wherein said opening is adapted to be quickly opened by hand.

114. A catheter according to claim 101, wherein said base hub includes a catheter storage section having a length, wherein said length is less than 80% of a length of a catheter section stored therein.

115. An extendible catheter comprising:

a base section adapted to remain outside a human body, when the catheter is in use;

an elongate body having a lumen and a distal tip and including a collapsed section stored in said base section; and

a liquid column adapted to apply force to said body adjacent said tip.

REPLACED BY ART 34 AMDT

116. A catheter according to claim 115, wherein said collapsed section is stored in a folded configuration

117. A catheter according to claim 115, wherein said collapsed section is stored in an axially pleated configuration.

118. A catheter according to claim 115, wherein said collapsed section is stored in an coiled configuration

119. A catheter according to claim 115, wherein said collapsed section is stored in an axially folded configuration such that part of said section is inside-out.

120. A catheter according to claim 115, comprising an outer tube out of which said body exits in an uncollapsed state.

121. A catheter according to claim 115, comprising a second collapsed tube inside of said collapsed section.

122. A catheter according to claim 121, wherein said second collapsed tube is a balloon inflation tube.

123. A catheter according to claim 115, comprising a feeding nozzle for uncollapsing said collapsed section.

124. A catheter with a mechanically activated fluid valve, comprising:
an elongate body having a lumen, said lumen defining a fluid path;
a tool activated by said fluid and situated at a distal section of said elongate body;
a fluid valve at said distal section adapted to selectively convey fluid to said tool; and
a mechanical actuator coupled to said valve and extending outside of said body to control said valve.

125. A catheter according to claim 124, wherein said tool comprises a fluid-inflated balloon.

126. A catheter according to claim 124, wherein said catheter is adapted to have a distal section thereof extended distally by said fluid.

127. A catheter according to claim 124, wherein said actuator rotates said valve.

128. A catheter according to claim 124, wherein said actuator retracts a blocking section of said valve.

129. A catheter according to claim 128, wherein said actuator retracts a blocking section of said valve such that in a maximally retracted position the blocking section allows for passage of fluid from said lumen to said tool.

130. A method of deploying a catheter-carried tool, comprising:

inserting an extendible catheter into a blood vessel of a body; and

extending a distal section of the catheter to reach a target area, by at least a distance of 50 mm.

131. A method according to claim 130, comprising activating said tool at a distal end of said extended section.

132. A method according to claim 130, wherein said extending comprises extending by providing fluid pressure into said catheter.

133. A method according to claim 130, wherein said tool comprises a balloon.

134. A method according to claim 130, wherein inserting comprises inserting along a guide wire.

135. A method according to claim 130, wherein inserting comprises inserting through a guiding catheter/sheath.

136. A method according to claim 130, comprising advancing said catheter after said extending.

137. A method of testing a catheter, comprising:

attaching the catheter to a source of hydraulic pressure; and

increasing said pressure to extend a distal section of the catheter by at least 50 mm.